



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/483,504	01/14/2000	Min Teng	5686.200-US	8481

7590 04/09/2003

Steve T. Zelson, Esq.  
Novo Nordisk of North America, Inc.  
Suite 6400  
405 Lexington Avenue  
New York, NY 10174-6400

EXAMINER

PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 04/09/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/483,504

Applicant(s)  
Min Teng et al

Examiner  
SUDHAKER PATEL,D.Sc.Tech.

Art Unit  
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 17, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 17, 21, 26, 30, 36, 37, 52, 53, 65, and 66 is/are pending in the application.
- 4a) Of the above, claim(s) 3 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6, 17, 21, 26, 30, 37, 52, 53, 65, and 66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

Art Unit: 1624

### DETAILED ACTION

Applicants' communication paper # 9 dated 3/17/03 is acknowledged.

#### *Election/Restriction*

**I.** Because applicants did not distinctly and specifically point out the supposed errors in the restriction/election requirement, the election has been treated as an election without traverse(MPEP 818.03(a)).

Applicants have elected invention of Group III Claims(in part) 1-4, 6, 17, 21, 26, 30, 36, 37,52,53,65,66, drawn to compounds, simple compositions, and a method of use for the compounds of generic Formula (I) of claim 1, classified in class 544, subclasses 338,349,353,354,355,356; class 514, subclasses 183,249. Applicants also elected as species, the compound of Example 103 listed on page 109 of the specification. Accordingly, this application will be examined for the invention of Group III with the elected subject matter as defined above only.

The restriction/election is considered proper, and made FINAL.

The elected species represents following variables in the generic Formula (I) of claim 1:

R1 and R4	=Hydrogen atoms;
R2 and R3	=halogen atoms;
X	= (=N-);
V	= (=N-);

Art Unit: 1624

L	=-SO <sub>2</sub> -CH <sub>2</sub> -;
A	=H;
M	=-NR <sup>9</sup> - CH <sub>2</sub> -when n = 1;
R <sup>9</sup>	=H;
B	=H.

Applicants are reminded of the election of species guidelines provided in MPEP 803.02, which are followed for examination.

Preliminary examination did not reveal prior art for the elected species. However, further examination revealed art. (see rejections bellow).

As per the guidelines, the examination was limited to the variables as defined bellow:

R1 and R4	=Hydrogen atoms, Halogen, NO <sub>2</sub> , CF <sub>3</sub> ;
R2 and R3	=halogen atoms, H, NO <sub>2</sub> , CF <sub>3</sub> ;
X	= (=N-);
V	= (=N-);
L	=-SO <sub>2</sub> -CH <sub>2</sub> -, -S-, SH-, -NH <sub>2</sub> , -NH- or bond;
A	=H, or lower alkyl;
M	=-NR <sup>9</sup> - CH <sub>2</sub> -when n = 1, bond, -SO <sub>2</sub> -alkylene-, -S-alkylene-, -SO-alkylene-, NH-, -NH <sub>2</sub> --;
R <sup>9</sup>	=H, alkyl, cycloalkyl, heteroaryl;

Art Unit: 1624

B                                =H, or lower alkyl.

Based on above presentation, all other definitions of variables R1-R4, L,M,A,B are withdrawn from further consideration. Further more claims 3,36, are also withdrawn from further consideration.

Therefore, the examination of this application will consists of examination of claims( in part) 1-2,4, 6, 17, 21, 26, 30, 37,52,53,65,66 representing the subject matter as elected by the applicants and described earlier by defining the various variables.

**II.**                                ***Information Disclosure Statement***

The information disclosure statement paper # 6 submitted on 11/14/02 has been considered by the Examiner and a signed copy of the same is being enclosed with this communication for applicants' record.

**III.**                                ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1624

Claims 1-2,4, 6, 17, 21, 26, 30, 37 are rejected under 35 U.S.C. 102(a) as being anticipated by Sasse et al (EP 18493). Claim 1 of Sasse (see page 36 of specification) reads on to the compounds instantly claimed in the following way.

X <sub>n</sub> (= Halogen or NO <sub>2</sub> or CF <sub>3</sub> wherein n = 1-4 )	= Instant claim 1 (see page 170) wherein
	R <sub>2</sub> /R <sub>3</sub> are halogen or CF <sub>3</sub> or NO <sub>2</sub> , and
	R <sub>1</sub> /R <sub>4</sub> i.e positions 5 & 8 = H, halogen, CF <sub>3</sub> , NO <sub>2</sub> ;
Positions 1,4 are N	=X, V both are N;
Position 3 i.e. R' (=H/alkyl/cycloalkyl)	= L = Bond and A = H/lower alkyl/cycloalkyl);
Pos. 2 i.e. SO <sub>2</sub> -R (=alkyl/cycloalkyl/aryl)	=M(= -SO <sub>2</sub> -CH <sub>2</sub> -B wherein B = H.

**IV.*****Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2,4, 6, 17, 21, 26, 30, 37,52,53,65,66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

Art Unit: 1624

- (a). Claim 1 is recited as: “ compound of Formula (I) as well as any optical or geometrical isomer or tautomeric form thereof including mixtures of these or a pharmaceutically acceptable salt thereof”. Claim 1 is indefinite because above recitation implies more than what is being positively and definitely recited. The term “including mixtures of these “ can include any amount or ratio of various organic compound and hence it is not very clear as to what is being exactly claimed. Correction(s) to: “ or optical or geometrical isomers or tautomeric form or a pharmaceutically acceptable salt thereof” is required.
- (b). Claim 1 recites: “ optionally containing one or more”, “ may optionally be substituted with one or more”, “heterocyclic ring optionally containing one or more further”. It is not very clear as to what is being claimed by the applicants. More can be 2 or any number. Correction is required.
- (c). Claim 52 recites: “ at least one”, “one or more”. It is not exactly clear as what is being claimed. Correction to a compound of claim 1 and a pharmaceutically acceptable carrier” is required.
- (d). Claim 53 recites the dosage of a pharmaceutical composition wherein “ especially preferred amount is:”from about 0.5 mg to about 200 mg”. This reads as:” 0.1 mg to 40 mg” which is difficult to interpret with “about”. Correction is required.
- (e). Claim 65 recites: “a method for treatment and/or prevention”.. It is not very clear as to what is included by: “and/or”, and also the meaning of: “ treatment = prevention”.
- (f). Claim 66 recites: “ especially preferred ” 0.5 mg to 500 mg” per day of the compound of claim 1”. It is not very clear as to what applicants want to present with. In claim 53 (see rejection

Art Unit: 1624

(d) above) the amount of the compound in the composition is "0.5 mg to 200 mg". Therefore, it is very confusing to understand what is exactly being claimed. Correction is required.

V.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel, D.Sc.Tech. whose telephone number is (703) 308 4709.

The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah can be reached at (703) 308 4716 or Sr. Examiner Mr. Richard Raymond at 703 308 4523.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

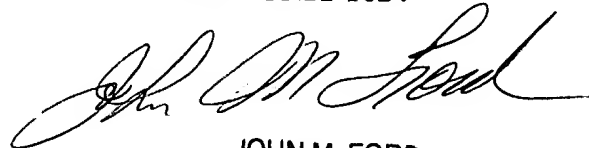
S.p.

April 4, 2003.

 MUKUND SHAH

SUPERVISORY PATENT EXAMINER

ART UNIT 1624

  
JOHN M. FORD  
PRIMARY EXAMINER  
GROUP - ART UNIT 1624